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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/438,759 | 11/11/1999 | GISELA MEIER | 2368/098 | 9841 |

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| EXAMINER | |
|---|---|
| LAM, ANN Y | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1641 | |

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/438,759 | MEIER ET AL. | |
| | Examiner | Art Unit | |
| | Ann Y. Lam | 1641 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *23 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *27-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/23/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

**1.** Claims 27, 30-35, 38, 39, 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krebs, 4,776,847.

As to claims 27, 41 and 42, Krebs discloses a cannula comprising: catheter (col. 1, line 41); an electrically conductive rigid hollow tube (i.e., "mandrel", col. 1, line 25, and lines 43-47) formed by a steel tube (col. 1, line 33) with a sharp tip (col. 1, line 32) with an exit opening (col. 1, line 24) dimensioned for passage of a catheter, a body part (i.e., proximal portion of conductive rigid hollow tube) including an inlet opening axially aligned with the cannula tube, wherein said cannula tube has an electrically insulating outer covering (plastic tube, col. 1, line 27) of the cannula tube which extends from the body part out to the tip and which leaves the tip exposed at least in its distal end area (col. 1, lines 29-30), wherein said electrical connector extends through the body part to the outer surface of the cannula tube (col. 1, lines 43-48; see also col. 3, lines 19-22), wherein the cannula is unipolar (col. 1, lines 43-51.)

The cannula described in column 1, lines 31-33 has an electrical connection for electrostimulation of nerve tissue to check the exact location of the cannula (col. 1, lines 43-51). However, it is not specifically disclosed as having a connector electrically connected to the cannula in the area of the body part. Krebs however discloses an improvement cannula wherein the steel tube is solid rather than hollow in order to avoid unnecessary of cutting tissue, and yet providing a puncturing tip (col. 2, lines 16-38.) Krebs further teaches that the improved cannula has a handle has an electrical plug-in socket for electro-stimulation at the tip to determine the position of the tip (col. 3, lines 19-23.) The electrical plug-in socket is equivalent to the claimed electrical connector. It would have been obvious to provide an electrical plug-in socket at the proximal end of the prior art cannula (i.e., the body part) to provide for an electrical connection as taught by Krebs as would be desirable for providing an electrical connection allowing for manipulation of a cannula and yet providing for electrical connection for electro-stimulation.

Also, as to claim 30, Krebs does not disclose a ring gap is formed between the proximal end of the cannula tube and the thereto connected electrically contacting connector and an inner wall of the body part, and wherein said ring gap is filled with plastic.

However, it would have been obvious matter of design choice to modify the Krebs teachings to include a ring gap filled with plastic, since applicant has not disclosed that the ring gap solves any stated problem or is for any particular purpose

and it appears that the Krebs device without a ring gap would perform equally well as with a ring gap.

As to claims 31 and 32, although the cannula disclosed in column 1, lines 31-33 is disclosed as being used to deliver anesthesia or for the introduction of a catheter (col. 1, line 41), it is not disclosed as having a body part at the proximal end of the hollow tube wherein the body part has an inlet opening decreasing in diameter to form an inlet funnel oriented co-axially towards the proximal end of the hollow tube, nor a Luer-lock connection at the proximal end of the body part. Krebs however discloses an improved cannula in column 4, lines 24-27, the cannula also having a plastic tube (10). Krebs further discloses that the plastic tube (10) has a shaft portion (12) at the proximal end of the plastic tube, the shaft portion having a larger diameter at its proximal end (col. 4, lines 36-37 and line 40.) The plastic tube (10) and shaft portion is used to deliver anesthesia or to introduce a catheter therethrough for a medical procedure (col. 3, lines 35-36.) It would have been obvious to one of ordinary skill in the art to provide a shaft portion disclosed in column 4, line 36, in the cannula disclosed in column 1, lines 31-33, as would be advantageous in facilitating delivery of anesthesia or introduction of a catheter.

As to claims 33, 38, Krebs does not disclose that the electrically exposed end area of the distal tip of the cannula tube has a length of maximally 1mm. However, Krebs teaches that the sharp tip of the rigid hollow tube is exposed from the plastic tube (col. 1, lines 28-30.) It would have been obvious to one of ordinary skill in the art to expose the tip of the rigid hollow tube to a length of maximally 1mm since such a range

of lengths is an optimum or workable range and it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

As to claims 34, 35, 39, the sharp distal tip of the cannula disclosed in column 1, lines 31-33 is not disclosed specifically as a facet cut at an angle of approximately 45 degrees to the axis of the cannula tube. However, Krebs discloses an improvement cannula in column 2, lines16-17, and specifically discloses that the sharp puncturing tip forms an angle of at least 45 degrees with the cannula (col. 2, lines 21-22.) It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the tip of the cannula in column 1, lines 31-33 with an angle of specifically 45 degrees, as a well known and conventional cannula tip angle for piercing tissue.

**2.** Claims 28, 29, are rejected under 35 U.S.C. 103(a) as being unpatentable over Krebs, 4,776,847 in view of Mower et al., 4,765,341.

Krebs discloses the invention substantially as claimed (see above), except for an electrical contact pressed against the cannula tube, to which contact a wire of a multi-strand connector is soldered.

However, Mower et al. disclose a medical device having an electrode and an electrical contact connected to a wire of a multi-strand connector. Mower et al. teach that the multi-strand connector provides flexibility and has an exceedingly long life in the face of mechanical stress, see column 5, lines 45-56. It would have been obvious to

provide a multi-strand connector as taught by Mower et al. as the connector in the Krebs device in order to provide for flexibility and to endure mechanical stress which is desirable for lasting use as taught by Mower et al.

**3.** Claims 36, 37, 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krebs, 4,776,847, in view of Haindl, 4,889,529.

Krebs discloses the invention substantially as claimed, see above, except for the distal tip being formed as a closed conically arched tip with an exit opening, or a ramp is formed on the inside of the distal end of the cannula tube, or a Sprotte tip.

Haindl discloses a needle having having a closed conically arched tip with an exit opening and a ramp formed on the inside of the distal end, such a needle having the advantage of piercing tissue with no material being punched out of the material to be perforated (see abstract.) It would have been obvious to form the sharp tip in the Krebs cannula having the configuration as taught by Haindl, such a tip having the advantage of preventing material being punched out of the material to be perforated.

***Response to Arguments***

Applicant's arguments with respect to the above claims have been considered but are moot in view of the new ground(s) of rejection. Examiner would like to point out that the Stoianovici device includes a catheter and a cannula that is unipolar (i.e., has one electrode).

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L

LONG V. LE
SUPERVISORY PATENT EXAMINER
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12/10/04